

Applicants: Peter David East and Susan Elizabeth Brown
U.S. Serial No.: 10/590,539
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REMARKS

Claims 1, 5, 6, 8-18, 20, 21, 23, 25, and 27 were pending in the subject application. Claims 1, 5, 11, 12, 14, 16-18, 20, 21, 23, 25, and 27 were withdrawn from consideration by the Examiner as being drawn to nonelected inventions.

Applicants have hereinabove amended claims 1, 6, 11, 15, and 17 and have added claims 28-29.

Support for the amendment to claims 1, 6, 11, 15 and 17 to require 80% identity to the recited sequence is to be found, *inter alia*, in the description as filed at page 8, line 33. Support for the amendment to claim 6 to recite the features of claim 1 is to be found in claim 1 as filed. Support for the amendment to claim 6 to require that the polynucleotide encodes a peptide having antifungal and/or antibacterial activity is to be found, *inter alia*, in the description as filed at page 6, lines 1 and 2. Support for newly added claim 28 is to be found, *inter alia*, in the description as filed at page 2, lines 11-33. Support for newly added claim 29 is to be found, *inter alia*, in the description as filed at page 2, lines 11-33, page 5, lines 17-37, and page 6, lines 1-9.

Applicants have also amended claims 1, 11 and 15 to delete reference to the term "fragment" in the final clause of the claim. Applicants maintain that the recitation in clause ix) that the claimed peptide includes biologically active fragments encompasses the deleted subject matter.

Election/Restriction

The Examiner has maintained his allegation that claims defining peptides and claims defining nucleic acids constitute different inventions and that each of the exemplified sequences constitutes a separate invention.

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Turning first to the Examiner's allegation that claims 1, 5, 12 and 27 (defining peptides) and claims 6, 8-10 and 13 (defining nucleic acids) constitute separate inventions, this application is a '371 US national phase application and, as a consequence, unity of invention must be assessed under PCT Rule 13. Annex B of Appendix AI entitled "Administrative instructions under the PCT" of the Manual of Patent Examining Procedure provides detailed guidelines for the determination of unity of invention for "371" US national phase application. Annex B provides a number of examples where the determination of unity of invention varies between Rule 13 of the PCT Regulations and US practice. Section (1) directs the Examiner to the "PCT International Search and Preliminary Examination Guidelines" which provides further examples of how the principles of Rule 13 should be applied. Chapter 10 of the PCT International Search and Preliminary Examination Guidelines relates to unity of invention. Paragraphs 10.20 to 10.59 provide yet further detailed examples of the determination of unity of invention under PCT Rule 13. As discussed in Section 10.59, where there is no prior art disclosing the claimed polynucleotide or peptide, the claimed polynucleotide and peptide share a corresponding technical feature. "Consequently, the claims have unity of invention (*a priori*)".

As discussed previously, the prior art relied on by the Examiner to support his allegation of lack of unity of invention (Schuhman et al., *Arch. Insect. Biochem. Physiol.*, 53: 125-133, 2003) discloses a peptide having 33.3% sequence identity to SEQ ID NO: 4 over a very small 12 amino acid stretch (rather than the entire sequence) and about the same level of identity to other sequences defined in claim 1. In contrast, the claims as amended require at least 80% identity. Accordingly, there is no prior art disclosing the sequences recited in claims 1, 5, 6, 8-10, 12, 13 and 27 and in applying the PCT Guidelines discussed above, claims defining peptides and polynucleotides must have unity of invention (*a*

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priori). The same principle applies to claims defining host cells, non-human animals, vectors and processes making use of the claimed peptides, polypeptides, plants and for making the claimed peptides.

As for the Examiner's contention that each sequence constitutes a separate invention, applicants submit that each of the claimed peptides is an alternative in a class of peptides sharing a common property and a common structure. For example, as discussed at page 42 of the instant application, the peptides of the present invention share a long linear alpha-helical tertiary structure, part of which is amphipathic. Furthermore, the claimed peptides are similar at the amino acid level as evidenced by the specification including a consensus sequence for the peptides of the invention (SEQ ID NO:62). The claimed polynucleotides also share a common property because they encode peptides having the shared common property and structure. Moreover, as previously discussed, this structure is entirely different to that of the defensin peptide/nucleic acid disclosed in the prior art relied on by the Examiner to support his allegation of lack of unity of invention. Accordingly, the sequences defined in the claims constitute a proper Markush group as required in Annex B paragraph f of Appendix AI entitled "Administrative instructions under the PCT" of the Manual of Patent Examining Procedure. As discussed in that section, if the alternatives claimed share a common property or a common structure, they shall be considered "of a similar nature" and "the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2 shall be considered to be met".

Finally, the Examiner's assertion that the technical feature linking each of the sequences is that they are antimicrobial peptides from *Galleria mellonella* overlooks the feature that these peptides are related peptides from *G. mellonella*, which belong to a separate class of peptides to the defensin peptide of the prior art and is